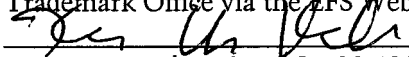


IN THE UNITED STATES PATENT AND TRADEMARK OFFICECERTIFICATE OF ELECTRONIC TRANSMISSION

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 Kevin M. Kercher, Reg. No. 33,408

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| In re Application of: James B. McCormick | : | Customer No. 021888 |
| | : | |
| U.S. Patent Application Serial No. 10/723,692 | : | Confirmation No. 8923 |
| Filed: November 26, 2003 | : | Examiner: Ramillano, Lore Janet |
| | : | |
| For: HISTOLOGICAL SPECIMEN | : | Group Art Unit: 1797 |
| RETAINING DEVICE | : | Attorney Docket No. 46521-56177 |

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicant requests that the Final Rejection of Claims 1-7 made in the Final Office Action Patent Office, dated November 10, 2008, be reviewed. Claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by Hartl et al. (U.S. Patent No. 4,225,557) in view of Roe et al. (U.S. Patent No. 6,060,039). Hartl et al. recites: "A packaged diagnostic test strip for determining occult blood in a stool sample, ...a back sheet supporting said test strip in layered arrangement with said test strip and with said front sheet, said back sheet having at least **one flap-covered aperture** therein in that region thereof ... **whereby when the flap is opened said test strip is exposed thereunder for application of peroxide solution** thereto to develop the reagent present in said test strip; and a **closure flap at least partially extending over said front sheet and having closure means thereon for covering said aperture in said front sheet when in closed position**" (emphasis added) (Claim 1, Column 4, Lines 36-37 and Lines 45-56). Therefore, in order to receive the peroxide solution, the closure flap needs to be open. The main argument put forth in the Final Office Action is that cardboard is inherently permeable. This is not a true statement. There are numerous examples of impermeable cardboard, e.g., U.S. Patent No. 4,204,820, issued to Toncelli on May 27, 1980; International Application No. PCT/IT91/0021 published to Della Pietra on October 3, 1991; U.S. Patent No. 6,079,555, issued to Posson on June 27, 2000; U.S. Patent No. 3,662,577, issued to Nicot on May 16, 1972; U.K. Patent Application No. 2,418,655 published to Snowden et al. on March 19, 2008; and U.S. Published Patent Application No. 20030026876 published to Mario Albuja on February 6, 2003. Therefore, the concept that the mere disclosure of the word "cardboard" inherently means that the cardboard is permeable is simply not true with numerous examples of impermeable cardboard in the prior art. Cardboard can be either permeable or impermeable based on the particular patent or technical publication reviewed. There mere fact that Roe et al. discloses permeable cardboard cannot be considered evidence of record establishing inherency. The reason

that no one skilled in the art can recognize that cardboard is either permeable or impermeable is that cardboard can be either depending on the type of cardboard. A clear reading of Hartl et al. indicates: "This part of the test can be performed by the patient himself. After closure, i.e. by insertion of the tab on the cover flap into the slit, the test slide goes to the doctor. **The latter opens the flaps on the back sheet and then applies the developer e.g. (peroxide solution) to the portions of the intermediate sheet, impregnated with the test reagent, which are so exposed and observes the results.** When guaicum resin is employed as an indicator in a test for occult blood in the stool, a blue to blue-green coloration indicates a positive result" (emphasis added) (Column 1, Lines 58-68). Therefore, the diagnostic test strip could be contaminated if the closure flap was permeable and it would be irrelevant as to whether or not the closure flap was open or closed. Therefore, the only reasonable interpretation, based upon a reading of Hartl et al., for a person of ordinary skill in the art, is that the cardboard disclosed in Hartl et al. is impermeable. The Invention disclosed in Hartl et al. would not function if the cardboard was permeable. No one skilled in the art would believe Hartl et al. could be made of permeable cardboard since the stool sample would be compromised by cardboard that allowed fluid to enter. In addition, the Final Office Action recites: "In response to applicant's agreement that Hartl et al. does not disclose a malleable securing strip but rather a slit, examiner respectfully disagrees. A claim must be interpreted in light of the specification without reading limitations into the claims. In Applicant's original disclosure, the claim language, "malleable securing strip," does not appear to be limited by a definition in the original disclosure since the original disclosure does not appear to clearly set forth the definition of such language explicitly and with reasonable clarity, deliberateness, and precision." (Final Office Action, Page 5, Lines 18-22 and Page 6, Lines 1-2). In marked contrast, Applicant's Published Patent Application in Paragraph [0028], Lines 1-7 recites: "Malleable securing strip 18 can be any **material** that is formable or malleable, but it is preferred that strip 18 is either a metal wire or a strip of heavy metal foil. The wire or foil needs to have appropriate dimensions to allow for a one time use-easy closure and clamping, as well as, positive release of extended flap portions 16a-d (described in more detail below)" (emphasis added). A slit is a: "...long, straight, narrow cut or opening." *The American Heritage® Dictionary of the English Language*, Fourth Edition, Copyright © 2006 by Houghton Mifflin Company. It is respectfully believed that a cut or opening is an absence of material, which does not involve a strip of material as clearly required and recited in the Applicant's patent application. Therefore, there is a very specific definition of "malleable securing strip" that requires "material" **that clearly precludes the use of a slit.** "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed.

Cir. 1987). In this case, a malleable securing strip made of material is an element that is not present in either Hartl et al. or Roe et al. Moreover, Claim 1 requires that the malleable securing strip is **attached** to the foldable permeable sheet. Attached is to "...fasten, secure, or join." *The American Heritage® Dictionary of the English Language*, Fourth Edition, Copyright © 2006 by Houghton Mifflin Company. A slit is a cut or opening and **is not material that is fastened, secured or joined to the foldable, liquid permeable sheet**. Therefore, it is respectfully believed that Claim 1 overcomes the rejection under 35 U.S.C. § 102(b) and is patentable over Hartl et al. in view of Roe et al. and is in condition for allowance.

Claims 2, 5 and 6 depend from independent Claim 1, which are respectfully believed to overcome the 35 U.S.C. § 102(b) rejection over Hartl et al. in view of Roe et al. in the same manner as Claim 1 as described above. If an independent claim is not anticipated, then any claim depending therefrom is also not anticipated. In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). Claim 2 recites that the "...malleable securing strip is attached at an edge of the liquid permeable sheet." Slits 18 and 18' are located away from the edge. An edge is the: "...line of intersection of two surfaces." *The American Heritage® Dictionary of the English Language*, Fourth Edition, Copyright © 2006 by Houghton Mifflin Company. The tab 17 would not be engageable with the slit 18 if it was truly located at the edge where front sheet 11 and rear sheet 14 meet but must be located away from the edge on the front sheet 11. Under 35 U.S.C. §102, "the identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). Claim 5 recites that: "...the liquid permeable target is coated with a release agent." The Examiner cites Column 3, Lines 46-47 of Hartl et al., which discloses a **reagent**. Applicant's Published Patent Application defines "release agent" as a parting layer of gluten, gelatin, casein, alginate, or similar organic coating (Paragraph [0023], Lines 8-10). It is respectfully believed that organic coatings are not reagents. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Therefore, it is respectfully believed that Claims 1, 2, 5 and 6 overcome the rejection under 35 U.S.C. § 102(b) and are patentable over Hartl et al. in view of Roe et al. and are in condition for allowance.

Claims 3 and 4 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hartl et al. (U.S. Patent No. 4,225,557) in light of Roe et al. (U.S. Patent No. 6,060,039), as stated above and further in view of Rochette (U.S. Patent No. 3,537,636). Claims 3 and 4 depend from independent Claim 1 and are respectfully believed to overcome the rejection over Hartl et al. in light of Roe et al. in the same manner as Claim 1 as described above. If an independent claim is not obvious, then any

claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). Moreover, as explained previously, the evidence is clear that cardboard is not inherently permeable and a permeable cardboard would destroy Hartl et al. for its intended purpose since the stool specimen needs to be protected from fluid contamination. Moreover, Rochette recites: "...a bag 10 fabricated from a sheet 11 of **cellulose film**" (emphasis added) (Column 1, Lines 64-65). This is the definition of CELLOPHANE®, which is a moisture proof (impermeable) film. *The American Heritage® Dictionary of the English Language*, Fourth Edition. Houghton Mifflin Company, 2004. "To reject a claim based on this rationale, U.S. Patent Office personnel must resolve the Graham factual inquiries. Office personnel must then articulate the following: (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, **with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference**; (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it did separately." (Federal Register / Volume 72, No. 195 / Wednesday, October 10, 2007 / Notices, Page 57529, "Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*") (emphasis added). In reality, the purpose of Hartl et al. of providing a packaged diagnostic test strip where the stool sample can be protected from fluid contamination in the closed position is very different than Applicant's Invention, as claimed, which requires histological examination fluid to pass through the foldable liquid permeable sheet. Rochette also appears to require a fluid impermeable material, i.e., CELLOPHANE®. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. *In re Kahn*, 441 F.3d 977, 986, 78 U.S.P.Q.2d 1329, 1335 (Fed. Cir. 2006). In this case, there is no reason to make the cardboard in Hartl et al. permeable. Moreover, the only reason that Roe et al. is cited is not because someone of ordinary skill in the art would be motivated to combine Hartl et al. with Roe et al. but merely that Roe et al. discloses permeable cardboard. It is respectfully believed that this is not a valid rejection since Hartl et al. clearly indicates that the packaged diagnostic test strip has impermeable front and back sheets since occult blood in a stool sample must react with a reagent and cannot be contaminated by outside liquid. Consequently, there is no reason to make the cardboard permeable in Hartl et al. since it would destroy Hartl et al.'s Invention. Therefore, it is respectfully believed that Claims 3 and 4 overcome the rejection under 35 U.S.C. § 103(a) and are patentable over Hartl et al. in view of Roe et al. and are in condition for allowance.

Claim 7 was rejected under 35 U.S.C. § 103 (a) as being unpatentable over Hartl et al. (U.S. Patent No. 4,225,557) in view of Roe et al. (U.S. Patent No. 6,060,039). Claim 7 depends from independent Claim 1 and is respectfully believed to overcome the rejection over Hartl et al. in light of Roe et al. in the same manner as Claim 1 as described above. If an independent claim is not obvious, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). Moreover, Applicant's Published Patent Application on Page 1, Paragraph [0013], Lines 1-6 recites: "The histological specimen retaining device may also comprise X and Y coordinate marking lines on the permeable target. The X and Y coordinate marking lines may allow for **proper orientation** of a tissue sample when placed on the target and serve as a **scalable reference for optional photographic imaging**" (emphasis added). In marked contrast, Hartl et al. shows two diagonal lines, i.e., Lines A-D and Lines B-C in FIG. 1, which are not along the X or Y-axis. Hartl et al. recites: "Providing that developer is applied on the reverse side of layer 13 to those areas thereof which correspond on the front side to the intersection of the diagonals A-D and B-C, the sites of **greatest color intensity on development will lie in the direction of these diagonals A-D and B-C**, shown in dotted lines in FIG. 1 for explanatory purposes" (emphasis added) (Hartl et al., Column 4, Lines 23-29). Therefore, diagonals are where the reagent most strongly reacts with the stool sample. This has no relationship to the orientation of tissue samples on a target for photographic imaging of the tissue samples. It is respectfully believed that the X and Y coordinates claimed by the Applicant are not disclosed by the diagonals in Hartl et al. and are for a very different purpose without the slightest hint or suggestion of this purpose provided by Hartl et al.

It is respectfully submitted that in view of the remarks presented herein, Claims 1-7 currently pending in the application are allowable over the prior art. It is respectfully requested that the Final Rejection of the Claims be withdrawn and the Claims allowed.

Respectfully submitted,

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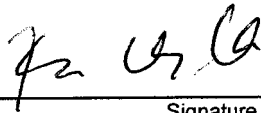
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| PRE-APPEAL BRIEF REQUEST FOR REVIEW | | Docket Number (Optional) 46521-56177 | |
|--|--|---|-----------------------------------|
| I hereby certify that this correspondence has been electronically filed with the U.S. Patent and Trademark Office via the EFS Web on January 20, 2009 Signature _____ Typed or printed name <u>Kevin M. Kercher</u> | | Application Number 10/723,692 | Filed November 26, 2003 |
| | | First Named Inventor McCormick, James B. | |
| | | Art Unit 1797 | Examiner Ramillano, Lore Janet |
| HISTOLOGICAL SPECIMEN RETAINING DEVICE | | Customer No. 021888 | Confirmation No. 8923 |
| <p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>33,408</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p> <p><input type="checkbox"/> *Total of _____ forms are submitted.</p> | | | |



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January 20, 2009

Date

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